

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

KINETIC CONCEPTS, INC.,
and KCI USA, INC.,

Plaintiffs,

v.

WAKE FOREST UNIVERSITY
HEALTH SCIENCES,

Defendant.

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CIVIL ACTION NO. 5:11-cv-00163

PLAINTIFFS' ORIGINAL COMPLAINT

Plaintiffs Kinetic Concepts, Inc. and KCI USA, Inc. (collectively "KCI") file this Complaint for a Declaratory Judgment and injunctive relief against Wake Forest University Health Sciences ("Wake Forest"). In support of its Complaint, KCI hereby alleges as follows:

I. PARTIES

1. Plaintiff Kinetic Concepts, Inc. is a corporation organized under the laws of the State of Texas, having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230.

2. Plaintiff KCI USA, Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 8023 Vantage Drive, San Antonio, Texas 78230. KCI USA, Inc. is a wholly owned subsidiary of Kinetic Concepts, Inc. KCI USA, Inc. sells the V.A.C. System in the United States.

3. Defendant Wake Forest is a non-profit corporation organized under the laws of the State of North Carolina, having its principal place of business at Medical Center Boulevard, Winston-Salem, North Carolina 27157. Wake Forest is a wholly controlled subsidiary of Wake Forest University.

II. JURISDICTION AND VENUE

4. This is a civil action for a Declaratory Judgment of noninfringement and/or invalidity of United States Patent Nos. 5,636,643 ("the '643 patent"), 5,645,081 ("the '081 patent"), 7,198,046 ("the '046 patent"), and 7,216,651 ("the '651 patent") (collectively "the Patents-in-Suit"). KCI further seeks a Declaratory Judgment concerning the rights and obligations of KCI under the terms of the License Agreement, including the payment of royalties under the License Agreement, if any.

5. This Court has subject matter jurisdiction over this action pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and 28 U.S.C. §§ 1331, 1338(a), and 1367(a).

6. This Court has personal jurisdiction over Wake Forest. Wake Forest has had systematic and continuous contacts with residents of Texas and this Court. For example, by entering into an exclusive license agreement with KCI, Wake Forest purposefully directed its activities at a Texas resident and this action results from injuries arising from those activities. Wake Forest has also purposefully directed its activities at a Texas resident by continuously seeking and receiving royalty payments from KCI under the License Agreement and this action results from injuries arising from those activities. Furthermore, Wake Forest has consented to

personal jurisdiction in this Court by filing patent infringement actions against third-parties relating to the Patents-in-Suit.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c).

III. BACKGROUND

8. KCI is a leader in the development, manufacture and distribution of specialty therapeutic medical devices. Several of KCI's product lines feature products that provide wound care benefits for patients in the United States and around the world. KCI's wound care product lines include variations of the Vacuum Assisted Closure[®] Therapy System, also known as the "V.A.C.[®] Therapy System" (hereinafter, "V.A.C. System"). The V.A.C. System is used in every major medical center in the world and has been used to treat over four million patients worldwide.

9. Effective October 14, 1993, KCI and Wake Forest entered into an agreement ("the License Agreement") granting KCI exclusive rights to certain United States and foreign patents purportedly owned by Wake Forest, including the Patents-in-Suit, that relate to wound treatment by maintaining reduced pressure on a wound to promote healing of the wound (collectively "the Licensed Patents").

10. Under the License Agreement, Wake Forest's earned royalty is based on sales of KCI products in a given country that are covered by the Licensed Patents issued to Wake Forest in that country. Thus, no royalties would be owed to Wake Forest for sales of KCI products in the United States if this Court were to issue a Declaratory Judgment of invalidity and/or non-infringement for each claim of the Patents-in-Suit — which comprise all of the Licensed Patents issued to Wake Forest in the United States — that Wake Forest alleges to cover those sales.

11. Judicial tribunals in the United States and foreign countries have already adjudicated the validity of some of the claims of the Licensed Patents. For example, in *Kinetic Concepts, Inc. et al. v. Bluesky Medical Corp. et al.*, Civil Action No. 08-CV-102-WRF, this Court held that claims of the '081 and '651 patents were invalid under 35 U.S.C. § 103 for obviousness. In *Wake Forest University Health Sciences et al. v. Smith & Nephew PLC et al.*, Case Nos. A3 2009/931 and A3 2009/1227, the Supreme Court of Judicature (United Kingdom) held that claims of EP 0 620 720 were invalid for obviousness. Further, in consolidated cases *Medela AG Medical Technology and Smith & Nephew GmbH v. Wake Forest Univ.*, File No. 4 Ni 39/07, and *Mölnlycke Health Care AB v. Wake Forest Univ.*, File No. 4 Ni 16/08, the German Federal Patent Court held that all claims of EP 0 620 720 were invalid.

IV. CAUSE OF ACTION: DECLARATORY JUDGMENT ON CONTRACTUAL RIGHTS AND OBLIGATIONS

12. KCI hereby repeats and incorporates by reference the allegations set forth in Paragraphs 1 to 11 as though set forth herein in their entirety.

13. An actual controversy has arisen and now exists between KCI and Wake Forest concerning the rights and obligations of KCI under the terms of the License Agreement. Wake Forest has demanded that KCI pay royalties under the License Agreement on the erroneous belief that KCI's V.A.C. System is covered by the Patents-in-Suit, notwithstanding judicial decisions in the United States, the United Kingdom and Germany holding that several claims of the Licensed Patents were invalid. Because KCI's sales of the V.A.C. System are not covered by any valid and enforceable claim of the Patents-in-Suit, KCI does not owe royalty payments for sales of its V.A.C. System based on the Patents-in-Suit.

14. The basis for non-infringement and invalidity of the Patents-in-Suit arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*

15. KCI hereby seeks a declaratory judgment under 28 U.S.C. §§ 2201-2202 that it owes no royalties under the License Agreement for sales of its V.A.C. System based on the Patents-in-Suit.

V. CAUSE OF ACTION: DECLARATORY JUDGMENT OF INVALIDITY OF THE '643, '081, '046, AND '651 PATENTS

16. KCI hereby repeats and incorporates by reference the allegations set forth in Paragraphs 1 to 15 as though set forth herein in their entirety.

17. An actual controversy has arisen and now exists between the parties concerning the validity of the Patents-in-Suit.

18. KCI hereby seeks a declaratory judgment under 28 U.S.C. §§ 2201-2202 that the claims that cover its V.A.C. System are invalid.

VI. CAUSE OF ACTION: DECLARATORY JUDGMENT OF NONINFRINGEMENT AS TO KCI'S V.A.C. SYSTEM

19. KCI hereby repeats and incorporates by reference the allegations set forth in Paragraphs 1 to 19 as though set forth herein in their entirety.

20. An actual controversy has arisen and now exists between the parties concerning whether KCI's V.A.C. System infringes any valid and enforceable claim of the Patents-in-Suit.

21. KCI hereby seeks a declaratory judgment under 28 U.S.C. §§ 2201-2202 that its V.A.C. System does not infringe any valid or enforceable claim of the Patents-in-Suit.

VII. PRAYER FOR RELIEF

For these reasons, KCI asks for judgment against Wake Forest for the following:

- A. Declaring that KCI owes no royalties under the License Agreement for sales of its V.A.C. System based on the Patents-in-Suit;
- B. Declaring that KCI's V.A.C. System does not infringe any valid and enforceable claim of the Patents-in-Suit;
- C. Declaring that the Patents-in-Suit are invalid;
- D. Enjoining Wake Forest, its officers, agents, servants, employees and attorneys, and all persons in active concert or participation with any of them who receive actual notice of the injunction by personal service or otherwise from directly or indirectly charging infringement, or instituting any action for infringement of the Patents-in-Suit against KCI and/or any of its affiliates, customers, licensees or potential customers or licensees with respect to the V.A.C. System;
- E. Declaring this case to be exceptional within the meaning of 35 U.S.C. § 285 and awarding KCI the attorney fees, costs, and expenses that it incurs in connection with this action; and
- F. Awarding KCI such other and further relief as the Court deems just and proper.

February 28, 2011

Respectfully submitted,

/s/ Stephen P. Allison

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